

REMARKSInterview Summary

Applicants thank the Examiner for the telephone interview on March 31, 2010. The Applicants' representative and the Examiner discussed claim 64, and the Examiner indicated that a non-final action was being prepared comprising a new ground of rejection over art. Applicant's representative requested that the Examiner make the new ground of rejection of record in the office action.

Interview Request

Applicants respectfully request a telephonic interview after the Examiner has reviewed this response. Applicants request the Examiner call Applicants' representative at telephone number (760) 473-9472.

Claim Status

Applicants herein amend claims 64, 65, 70, and 71. The amendments find basis in the claims as originally filed and in the specification throughout. Accordingly, no prohibited new matter is introduced by entry of the amendments herein.

Summary of outstanding claim rejections

Applicants acknowledge the withdrawal of rejections under 35 U.S.C. 112. The Office rejected claims in the outstanding action for alleged indefiniteness under 35 U.S.C. 112, second paragraph, and for alleged obviousness under 35 U.S.C. 103(a), which are summarized hereafter:

- i. Claims 64, 65, 70, and 71 were rejected under 35 U.S.C. 112, second paragraph, for alleged indefiniteness;
- ii. Claim 64 was rejected under 35 U.S.C. 103(a) for alleged obviousness over Green et al. (U.S. Patent No. 5,853,979), in view of Dunkel (U.S. Patent No. 5,572,125), in view of Ferrige et al. Rapid Communications in Mass Spec. 5:374-77 (1991) , and in view of Leung et al. (Anal. Chem., Vol. 70, p. 5222-5229, 1998);

- iii. Claims 79 and 92 were rejected under 35 U.S.C. 103(a) for alleged obviousness over Green et al., in view of Dunkel, and in view of Croft et al. (Journal of Biomolecular NMR, Vol. 10, p. 207-219, 1997);
- iv. Claims 82-83 and 93 were rejected under 35 U.S.C. 103(a) for alleged obviousness over Green et al. in view of Dunkel, in view of Croft et al. as applied to claim 79 and 92 above, and further in view of Mir et al. (Annual review of Genomics and Human Genetics Vol. 1, 329-360, 2000).

The claim amendments herein are introduced solely to expedite prosecution without prejudice or disclaimer of any previously claimed subject matter. Applicants have not dedicated or abandoned any unclaimed subject matter and have not acquiesced to any rejections or objections made by the Office by introducing the amendments herein. Applicants expressly reserve the right to pursue prosecution of any presently excluded or cancelled subject matter or embodiments in one or more future continuing patent applications.

Rejection for Alleged Indefiniteness Under 35 U.S.C. 112, Second Paragraph

Claims 64, 65, 70, and 71 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection respectfully is traversed in its entirety, including all reasons and rationale for the rejection, and Applicants respectfully submit that the rejection is inapplicable to the claims herein.

Claims 64 and 65 were rejected as unclear with respect to the step of compression of the intermediate data set. The Office stated that it is “unclear what relationship is intended between the compressed data set and the process of identifying a component” and that it is “unclear what role the step of compression has in the process.”

Claims 64 and 65 have been amended to clarify the integration of the data compression step with the rest of the claim. Support for these amendments may be found, for example, in the pre-amended version of the claims, as well as in the specification at page 15, line 12 to page 17, line 4, and in Figure 2.

Claim 70 was rejected as unclear with respect to the claim disclosing that an area of twice the width of the Gaussian is removed from the left of center of each putative peak. The Office stated that the claim “does not disclose at which point in the process the area of twice the width of the Gaussian is removed” and that it is “unclear which step the removal of the area is associated, thus making the metes and the bounds of the claim unclear.”

Claim 70 has been amended to clarify the step of generating the residual baseline. Support for this amendment may be found, for example, in the pre-amended version of the claims, as well as in the specification at page 18, lines 4-14, and in Figure 22. In making this amendment, Applicants do not concede that the original language was unclear.

Claim 71 was rejected as unclear with respect to the removal of an area of 50 Daltons from the right of center from each putative peak. The Office stated that “The claim does not disclose at which point in the process the area is removed or with which step the removal is associated.” The Office further stated that the claim is “unclear with respect to the area of 50 Daltons because the claim does not provide a measure of scale relative to the data and the area,” and that the “lack of a frame of reference for the area makes the removed area indefinite.”

Claim 71 has been amended to clarify the step of generating the residual baseline. Support for this amendment may be found, for example, in the pre-amended version of the claims, as well as in the specification at page 18, lines 4-14, and in Figure 22. In making this amendment, Applicants do not concede that the original language was unclear.

Rejection of Claim 64 for Alleged Obviousness Under 35 U.S.C. 103(a)

Claim 64 was rejected under 35 U.S.C. 103(a) as unpatentable over Green et al. (U.S. Patent No. 5,853,979, in view of Dunkel (U.S. Patent No. 5,572,125), in view of Ferrige et al. (Rapid Communications in Mass Spec. 5:374-77 (1991)), and in view of Leung et al. (Anal. Chem., Vol. 70, p. 5222-5229, 1998). The rejection respectfully is traversed in its entirety, including all reasons and rationale for the rejection, and Applicants respectfully submit that the rejection is inapplicable to the claims herein.

Claim 64, as presently amended, includes the step of compressing the intermediate data set to obtain compressed data. The compressed data comprise compressed data

points, wherein a compressed data point is a real number that includes a whole number portion that is determined by calculating the difference between the whole number portions of two consecutive points in an array of data. Support for the present amendment may be found throughout the specification, for example, in Figures 18 and 19, and at page 15, line 12 to page 17, line 4.

The Office stated that Green et al. “teach a method, a computerized system, system, and machine-readable program operating on a computer for identifying a component in a DNA sample using a mass spectrometer to generate a machine readable data set and analyzing the data by performing noise reduction to generate denoised data, correcting a baseline for the denoised experimental data representing an intermediate data set, defining peaks in the intermediate data set as “fragment pattern” and “shows spectra can be ‘normalized’ with fourth order polynomials.” The Office also stated that Green et al. “teach the computer is integral to the instrument.” The Office noted that “Green et al. do not teach the removal of peaks and subsequent generation and removal of a residual baseline from the denoised experimental data.”

The Office found that Dunkel teaches a “method of automated analysis and correction of spectral data obtained through ion cyclotron mass spectrometry,” and cited Dunkel as teaching that “the residual baseline obtained by removing peaks from experimental data can be applied to the experimental data to correct for baseline distortion,” and teaching the “generation of a residual baseline by subtracting modeled peak data from the experimental ‘intermediate’ data.” The Office noted that Green et al. in view of Dunkel does not show a step of data compression.

The Office cited Ferrige et al. as showing a “mass spectrum deconvolution method called the maximum entropy (MaxEnt) technique,” and “shows that the MaxEnt technique compresses the intermediate data.” The Office cited Leung et al. as showing “that wavelet transforms are a technique of data compression.”

The Office stated that it “would have been obvious to one of skill in the art to combine the method for correction of spectral data of Dunkel with the method of intermediate data set generation of Green et al. because Green et al. teach that other signal processing techniques can be applied to generate clean, corrected data and Dunkel teaches that baseline correction can be corrected by subtracting the residual baseline.” The

Office further stated that it would have been obvious to “modify the method..with the MaxEnt deconvolution technique.” The Office further stated that it would have been obvious to modify the method with the wavelet transform technique for data compression of Leung et al. “because Leung et al. shows the major advantage of the proposed method is that it can perform numerical differentiation and noise reduction in the same calculation and can enhance the signal-to-noise ratio for even higher order derivatives.”

None of the references cited by the Office include the step of claim 64 of compressing the intermediate data set to obtained compressed data, where the compressed data comprise compressed data points and wherein a compressed data point is a real number that includes a whole number portion that is determined by calculating the difference between the whole number portions of two consecutive points in an array of data. Neither the Ferrige et al. nor the Leung et al. references teach this method of data compression. Applicants therefore respectfully request that the Office withdraw the rejection of claim 64.

Rejection of Claims 79 and 92 for Alleged Obviousness Under 35 U.S.C. 103(a)

The rejection respectfully is traversed in its entirety, including all reasons and rationale for the rejection, and Applicants respectfully submit that the rejection is inapplicable to the claims herein.

Claims 79 and 92 require the use of a mass spectrometer, and each claim includes the step of determining a peak probability for a located putative peak, and multiplying the peak probability by an allelic penalty to obtain a final peak probability.

Claims 79 and 92 were rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al., in view of Dunkel, and in view of Croft et al. (Journal of Biomolecular NMR, Vol. 10, p. 207-219, 1997). The Office’s analysis of Green et al., and Dunkel, was essentially the same as that for Claim 64, re-stated above. The Office noted that Green et al. in view of Dunkel “does not show determining a peak probability.” The Office cited Croft et. al. as showing a method of “automated peak assignment from spectrometer data.” The Office stated that it would have been “obvious to one of ordinary skill in the art at the time of invention to modify the method of identifying a component in a sample using the mass

spectrometer of Green et al. in view of Dunkel with the method of peak filtering based on penalized peak probabilities of Croft et al. because Croft et al. shows filtering peaks by peak probability advantageously reduces large lists of peaks to a manageable size and ensures that the correct results are more likely to be the highest scoring ones.”

Croft et al. relates to the analysis of data obtained by NMR to assign spin to peaks representing protein residues. The Office has not pointed out any teaching or motivation in either Green et al., or Dunkel et al., to seek the use of methods associated with NMR analysis for mass spectrometry methods. Applicants therefore respectfully contend that claims 79 and 92 are not obvious over the art cited by the Office, and request that the rejection of these claims be withdrawn.

Rejection of Claims 82-83 and 93 for Alleged Obviousness Under 35 U.S.C. 103(a)

The rejection respectfully is traversed in its entirety, including all reasons and rationale for the rejection, and Applicants respectfully submit that the rejection is inapplicable to the claims herein.

Claim 82, 83, and 93 require the use of a mass spectrometer, and each claim includes the step of determining a peak probability for a located putative peak, and multiplying the peak probability by an allelic penalty to obtain a final peak probability.

Claims 82-83 and 93 were rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. in view of Dunkel, in view of Croft et al. as applied to claim 79 and 92 above, and further in view of Mir et al. (Annual review of Genomics and Human Genetics Vol. 1, 329-360, 2000). The Office’s analysis of Green et al., Dunkel, and Croft et al. was essentially the same as that for Claims 79 and 92, re-stated above. The Office noted that Green et al. in view of Dunkel in view of Croft et al. do not show a calling ratio. The Office stated that Mir et al. “shows methods for the large scale analysis of sequence variation in genes and genomic DNA,” and “shows that a calling ratio is determined by comparing the highest peak to the next highest peak.” The Office stated that it would have been “obvious to one of ordinary skill in the art to modify the method of identifying a component in a sample using the mass spectrometer of Green et al. in view of Dunkel and the method of peak filtering based on penalized peak probabilities of Croft et al. with the determination of

a calling ratio of Mir et al. because Mir et al. shows that allelic variation is advantageously and successfully determine the ratiometric changes in hybridization pattern of peak intensity.

Croft et al. relates to the analysis of data obtained by NMR to assign spin to peaks representing protein residues. The Office has not pointed out any teaching or motivation in either Green et al., or Dunkel et al., to seek the use of methods associated with NMR analysis for mass spectrometry methods. Applicants therefore respectfully contend that claims 82, 83, and 93 are not obvious over the art cited by the Office, and request that the rejection of these claims be withdrawn.

CONCLUSIONS

It is respectfully submitted that all outstanding objections and rejections have been addressed. The absence of a reply to a specific issue or comment presented by the Office does not signify that Applicants agree with or concede to that issue or comment. Because arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims, or other claims, that have not been expressed. Nothing in this submission should be construed as an intent to concede any issue with regard to any claim, except as specifically stated herein.

In view of the foregoing amendments and remarks, Applicants respectfully submit that the Office can properly withdraw the outstanding claim rejections and that the pending claims herein are in condition for allowance. Applicants therefore respectfully request that the Office withdraw the outstanding claim rejections and issue a notice of allowance.

Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this patent application. Applicants' representative can be contacted by telephone at (760) 473-9472.

In the unlikely event a fee calculation document or other pertinent document is separated from this submission and the Office determines that an extension and/or other relief is required, Applicants petition for any required relief, including extensions of time, and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **50-3473**.

Respectfully submitted,

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